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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/896,053	07/17/1997	STEFAN JANSSENS	0609.4280001	2698

7590

12/19/2001

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EXAMINER

BECKERLEG, ANNE M 25

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/896,053

Applicant(s)

JANSSENS ET AL.

Examiner

Anne M Beckerleg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-25, 28-33, 35 and 37-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-24, 28-32, 35 and 42 is/are allowed.
- 6) ☒ Claim(s) 37-41 and 43 is/are rejected.
- 7) ☒ Claim(s) 25 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 25.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The finality of the previous office mailed on 1/17/01, paper no. 22, has been withdrawn for the following reasons. In a telephone interview between the examiner and Lawrence Bugaisky, the applicant's representative pointed out that the advisory action issued on March 16, 2000 indicated that the "proposed amendments would not be entered because they raise new issues that would require further consideration and/or research". The new issue concerned the breadth of proposed claims 40-41 which did not limit the delivery of the vector to the lungs. Following entry of the proposed claims, the examiner addressed the increased breadth of the claims under 35 U.S.C. 112. In view of the previous statement that the broad recitation of any delivery site raised a new issue, the finality of the previous office action is withdrawn.

Applicant's amendment received on 7/23/01 has been entered. Claims 26-27, 34, and 36 have been canceled without prejudice. New claims 42-43 have been added. Claims 22-25, 28-33, 35, and 37-43 are pending in the instant application. An action on the merits follows.

The text of those sections of Title 35, US code, not included in this action can be found in the previous office actions.

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The objection to the oath or declaration is maintained. The examiner acknowledges the applicant's previously stated intent to correct the defects in the declaration until such time that allowable subject matter has been indicated.

Claim Rejections - 35 USC § 112

The rejection of claims 22-41 under 35 U.S.C. 112, first paragraph, for scope of enablement is withdrawn over claims 22-39 in view of applicant's amendment or cancellation of the claims. However, claims 40-41 remain rejected under 35 U.S.C. 112, first paragraph, for reasons of record as discussed in detail below. Applicant's arguments as they apply to the remaining grounds of rejection have been fully considered but they are not persuasive in overcoming the instant grounds of rejection.

Claims 40-41 recite methods of inducing pulmonary vasodilation comprising: administering to a mammal a composition comprising a nucleic acid encoding nitric oxide synthase and an effective amount of an immunosuppressive agent or a phosphodiesterase inhibitor. The specification, while being enabling for methods of inducing vasodilation in a mammal comprising: introducing into the lungs of a mammalian patient in need of pulmonary vasodilation an aerosolized adenoviral vector comprising a nitric oxide synthase gene operably linked to expression control elements, wherein the introduction of said gene into the lungs of said patient results in pulmonary vasodilation that does not significantly affect systemic blood pressure

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or cardiac index, does not reasonably provide enablement for a method of inducing pulmonary vasodilation in all mammals comprising introducing by any route of delivery an adenoviral vector encoding nitric oxide synthase gene in combination with any immunosuppressive agent or any phosphodiesterase inhibitor.

The applicant states on page 13 of the response that while the applicants disagree with the Examiner's arguments regarding the lack of enablement for using any route of delivery to induce pulmonary vasodilation *in vivo*, in the effort to expedite prosecution, the applicants have amended the claims to recite "aerosolized adenoviral vector". While it is true that claims 22-39, and 42-43 have been amended to recite the delivery of aerosolized adenoviral vector encoding NOS to the lungs of a mammal, claims 40-41 continue to recite the administration of adenoviral vector encoding NOS using any route of administration. As the applicant has not provided any specific arguments regarding this grounds of rejection, the rejection of record is maintained over claims 40-41.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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Claims 37-39 and 43 are newly rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,880,102 (3/9/99), hereafter referred to as George et al. The applicant claims a pharmaceutical composition suitable for aerosol delivery comprising an adenoviral vector encoding a nitric oxide synthase gene operably linked to expression control elements. The applicant further claims said compositions wherein the nitric oxide synthase gene is endothelial nitric oxide synthase, or wherein the adenovirus vector is Ad CMV eNOS.

George et al. teaches recombinant adenoviral vectors encoding an NOS isoform operatively linked to a CMV promoter (George et al., column 77, claims 13 and 25, and column 78, claims 26-28). George et al. further teaches that the NOS isoform is endothelial NOS (George et al., column 5, lines 32-44). George et al. also teaches the use of said recombinant adenoviruses encoding NOS for *in vivo* administration in a mammal for the treatment of diseases such as vein graft failure and restenosis (George et al., columns 5-6). In addition, George et al. teaches the administration of an adenoviral vector encoding NOS in saline, a pharmaceutically acceptable carrier which is further suitable for aerosol delivery (George et al., column 6). Thus, by teaching all the elements of the claims, George et al. anticipates the instant invention.

Please note that although George et al. does in fact teach the intended use of the disclosed adenoviral vectors for pharmaceutical use *in vivo*, the intended use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that, "... in apparatus, article, and composition claims, intended use must

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result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." In re Casey, 152 USPQ 235 (CCPA 1967); In re Otto, 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02).

Claims 25 and 33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of claims 22 and 28 respectively. Claims 25 and 33 depend on claims 22 and 28 respectively and further recite wherein the nitric oxide gene is transduced into the lungs in a viral vector. Claims 22 and 28 already recite wherein the nitric oxide synthase gene is encoded by an adenoviral vector. Thus, claims 25 and 33 do not further limit the parent claims. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Please be advised that amendment to the claims may result in new grounds of rejection.

Claims 22-24, 28-32, 35, and 42 are considered allowable at this time.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Beckerleg, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Karen Hauda, can be reached at (703) 305-6608. General inquiries should

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be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the group fax number is (703) 308-8724.

Dr. A.M.S. Beckerleg

**A.M.S. BECKERLEG
PATENT EXAMINER**

A handwritten signature in black ink, appearing to read 'A.M.S. BECKERLEG', followed by a large, stylized flourish or underline.